



The Soap and Detergent Association
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The Soap and Detergent Association and The Cosmetic, Toiletry, and Fragrance Association (SDA/CTFA Industry Coalition) provide these comments in advance of the October 20, 2005 meeting of the Nonprescription Drugs Advisory Committee. The SDA/CTFA Industry Coalition was established in 1994 to respond to the June 17, 1994 Tentative Final Monograph (TFM) for Health-Care Antiseptic Drug Products. Since that time the Coalition has worked to provide the Agency with current scientific data to support the premise that topical antimicrobial products are indispensable for infection control in the home, school and daycare situations. These products are necessary for the general population to reduce the risk of infection or acquisition of disease. We believe that topical antimicrobial products - when properly formulated to meet the log reductions for non-professional products cited in the TFM - are appropriate as long as standardized ASTM methods are used to assure accurate measures of efficacy. Furthermore the use of topical antimicrobial products in the home or healthcare setting does not contribute to the development of resistance or cross-resistance with antibiotics. Given changes in healthcare delivery and increasing reliance on non-hospital providers, consumers should be able to purchase and use topical antimicrobial products that are as effective as those used in the professional healthcare setting. The Coalition welcomes the opportunity to discuss the benefits and safety of using topical antimicrobial drug products as they represent a valuable tool for infection control – one that is recognized by other government and health agencies as well.

Critical Points

Consumer topical OTC antimicrobial products provide a public health benefit by reducing or eliminating bacteria on skin. These products are available in many forms (bars, liquids, gels, wipes etc.) and usually contain a single antimicrobial active ingredient. Currently, there are two major classes of consumer topical OTC antimicrobial drug products available in the U.S. market. These include:

- Antimicrobial hand and body washes, which generally have a broad spectrum of activity and are designed to reduce transient or resident organism populations and
- Hand sanitizers, waterless products which are used to kill bacteria on hands without soap and water

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The principal efficacy and safety features of both classes of products are presented below

Efficacy

- Topical OTC antimicrobial products provide consumers with an effective means of controlling the risks associated with exposure to or transmission of potentially pathogenic organisms
- The log reductions for non-professional antibacterial products as cited in the 1994 Tentative Final Monograph (TFM) (i.e., $2 \log_{10}$) are appropriate, as long as standardized ASTM methods (with neutralization of all sampling fluids) are employed in the Final Monograph
- These products are beneficial in a wide variety of situations where the risk of infection exists. These include in and out of home, school and daycare settings (i.e., caring for the sick or elderly, preparing meals, changing diapers, living in extended care facilities, etc.)
- The benefits of topical OTC antimicrobial drug products clearly support the current proposed labeling indication (i.e., “*to decrease bacteria on skin*”) and provide consumers with an effective means of controlling the risks of infection
- Efficacy of these products should be demonstrated after single use. The cumulative effect determination is not relevant in consumer (or healthcare) settings
- U.S. Federal, State, and local authorities, including the CDC, and leading health organizations, such as the World Health Organization (WHO) and the NIH, recommend the use of these products for infection control

Safety

- There is no clinical real-world evidence of increased resistance and/or cross-resistance under current use conditions of topical antimicrobial products
- Programs exist in the U.S. to monitor the possible emergence of antimicrobial resistance. These include the National Nosocomial Infections Surveillance (NNIS) program and the Interagency Task Force on Antimicrobial Resistance
- Extensive data on the environmental safety of individual active ingredients exist. Appropriate margin of safety values have been established and are available for public inspection

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